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APPLICATION NO.	FILING DATE	FIRST NAMED IN	VENTOR		TORNEY DOCKET NO.
09/471,825	12/23/99	LIN		S	2092/UG278
DARBY & DARBY PC 805 THIRD AVENUE NEW YORK NY 10022		НМ12/0329 ☐		EXAMINER HARRISON, R	
				1619	PAPER NUMBER

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

03/29/01

Application No. 09/471,825 Applicant(s)

Lin et al

Office Action Summary

Examiner

Group Art Unit Robert H. Harrison

1619

 □ Responsive to communication(s) filed on □ This action is FINAL. □ Since this application is in condition for allowance except for formal matter in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 4.1 A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to respond wapplication to become abandoned. (35 U.S.C. § 133). Extensions of time in 37 CFR 1.136(a). Disposition of Claims ☒ Claim(s) 1-55 Of the above, claim(s)	ters, prosecution as to the merits is closed 53 O.G. 213. one month(s), or thirty days, whichever within the period for response will cause the may be obtained under the provisions of is/are pending in the application.
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Of the above, claim(s)	
	ic/ore withdrawn from consideration
Claim(s)	is/are withdrawn from consideration.
	is/are allowed.
Claim(s)	
Claim(s)	
Application Papers	·
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PT	· ГО-948.
☐ The drawing(s) filed on is/are objected to by the	Examiner.
☐ The proposed drawing correction, filed on is ☐	_approveddisapproved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	•
Priority under 35 U.S.C. § 119	
\square Acknowledgement is made of a claim for foreign priority under 35 U.	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority	documents have been
received.	
received in Application No. (Series Code/Serial Number)	•
received in this national stage application from the International	
*Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 to the company of the compa	
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Attachment(s) Notice of References Cited, PTO-892	
Information Disclosure Statement(s), PTO-1449, Paper No(s).	
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	

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1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1619.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-53, drawn to a composition or dosage unit, classified in class 424,
 subclass(es) 484+.
- II. Claims 54 and 55, drawn to a method of preparing a composition and composition produced thereby, classified in class 427, subclass 2.21.

The inventions are distinct, each from the other because:

- 2. Inventions Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as pouring a mixture of the first and second aqueous solutions into a container.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

- 5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
- 6. This application contains claims directed to the following patentably distinct species of the claimed invention: (a) one single ultimate disclosed species of a first active, (b) one single ultimate disclosed species of a second active, (c) one single ultimate disclosed species of a water soluble polymer, (d) if required, one single ultimate disclosed species of fatty acid, (e) one single ultimate disclosed species of matrix forming agent.
- 7. Applicants' are further required to elect an ultimate working example that corresponds to the above elections as well as listing the claims readable thereon (see below) applicants' must list the claims that do not read on the ultimate working example, even if the requirement be traversed.
- 8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13-15, 19-26, 41-43, 45-47, and 49-55 are generic.
- 9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

- 10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 12. Claims 22 and 49 are generic to a plurality of disclosed patentably distinct species comprising (f) a preservative, (g) a flavorant, (h) an antioxidant, (i) a surfactant, (j) a sweetener, (k) a viscosity enhancer, (l) a colorant, (m) a fragrance, (n) a plasticizer, (o) a lubricant, (p) a filler, (q) a binder, (r) a wetting agent, (s) a penetration agent, (t) a pH adjuster, (u) a disintegrant, (v) an excipient. Applicant is required under 35 U.S.C. 121 to elect a single disclosed ultimate species, even though this requirement is traversed.
- 13. Should applicant traverse on the ground that the species are not patentably distinct as set forth in the immediately preceding paragraph, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record

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that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of

the other invention.

14. Applicants' are further required to elect an <u>ultimate working example</u> that corresponds to

the above elections - as well as listing the claims readable thereon and applicants' must list the

claims that do not read on the ultimate working example, even if the requirement be traversed.

15. A telephone call was made to Andrea Colby on March 14, 2001 to request an oral election

to the above restriction requirement, but did not result in an election being made.

16. Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37

CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

fee required under 37 CFR 1.17(I).

18. Any inquiry concerning this communication should be directed to Robert Harrison at

telephone number (703) -308-2422.

Harrison/LR

March 28, 2001

ROBERT H. HARRISON
PRIMARY EXAMINER
Group 1619

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